

Application No.: 10/540,829
Filing Date: February 21, 2006

REMARKS

Claims 1-19 and 21-26 are pending. Claims 12 and 14 are amended herein. Claim 12 is amended to remove enhanced solubility. Claim 14 is amended to clarify the subject matter. Support for the amendments can be found throughout the specification and claims as originally filed. No new matter is added.

Applicants submit that this application is in condition for allowance and such action is earnestly requested. Each of the Examiner's reasons for rejection is addressed below.

Rejections under 35 U.S.C. § 112

The Examiner continues to reject Claim 1 as indefinite for the use of the term "substantially nugget-free". The Examiner found that the scope of the claims would not be understood by one skilled in the art and that there is no evidence that one of ordinary skill in the art would understand what is meant by cheese that is "substantially" nugget-free. Office Action, pages 8-9. In response, Applicants submit evidence that a person of skill in the art would understand from the general knowledge in the art and from the specification that the term substantially nugget-free means nuggets are not present or are present in an amount that is not readily visible. Declaration of Skelte Gerald Anema, paragraph 11. Applicants respectfully request withdrawal of this rejection in view of the submitted evidence.

The Examiner rejected Claims 12 finding that the term "enhanced solubility" was indefinite. Without acquiescing in the rejection of Claim 12, Claim 12 is amended to remove "enhanced solubility", thereby obviating the rejection.

The Examiner rejected Claim 14 as indefinite for the use of "wherein the high denatured whey protein content is such that the whey protein content of curd produced". Without acquiescing in the rejection of Claim 14, Claim 14 is amended herein to recite wherein the whey proteins are denatured to allow 50-100% of the whey proteins to be incorporated into cheese following treatment with coagulation enzymes and separation of curds and whey. Applicants submit that Claim 14 is not indefinite and respectfully request withdrawal of the rejection.

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Delespaul Does Not Anticipate Claim 10

Claim 10 stands rejected under 35 U.S.C. § 102(b) as anticipated by FR 2452879 to Delespaul et al. (hereinafter "Delespaul").

Delespaul discloses ultrafiltration of milk until a desired concentration of protein is reached. Page 2, paragraph 3. Delespaul discloses subsequently processing the concentrated protein product with various additives to form cheese. See Examples.

Delespaul does not disclose **adding** the ultrafiltration retentate or a calcium depleted HY-MPC to a **milk containing fat**. Thus, Delespaul **does not** disclose "**adding** a 10-100% calcium depleted HY-MPC **to milk containing fat** or any other aqueous solution used as the starting material" as recited in Claim 10. Accordingly, Applicants request withdrawal of the anticipation rejection.

Further, in making the anticipation rejection the Examiner provides citations to multiple examples, a description of conventional cheese making using coagulation, a description of cheese manufacture using ultrafiltration, different methods for decalcification, and different methods for heat treatment. Office Action, pages 3-5. Even if all of the features of Claim 10 were present in multiple embodiments described in Delespaul, which they are not, such reliance on multiple embodiments and picking and choosing is inappropriate for an **anticipation rejection**. As the Federal Circuit has made clear:

Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. *See Arkley*, 455 F.2d at 587 ("[T]he [prior art] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.").

Net MoneyIn, Inc., 545 F. 3d 1359, at 1371 *citing In re Arkley*, 455 F.2d 586, 587 (CCPA 1972) (emphasis in original). Accordingly, Applicants respectfully request withdrawal of the anticipation rejection for this reason as well.

The Combination of Delespaul and Bhaskar Does Not Make Claims

Claims 1-9, 11-19, and 21-26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over WO 01/41578 to Bhaskar et al. (hereinafter "Bhaskar") in view of Delespaul.

The Examiner found Bhaskar to disclose the production of calcium depleted MPC. While the Examiner found that Bhaskar fails to disclose any heat treatment, Delespaul was found to disclose a heat treatment and the Examiner concluded that it would have been obvious to use the heat treatment in the processes of Bhaskar.

Bhaskar provides a method of making a dried MPC for use in a conventional cheese making process involving the separation of casein and whey. In contrast, the claimed processes allow for retention of the whey protein in the curd and subsequently the cheese.

Applicants submit that the combination of Bhaskar and Delespaul fails to disclose the features of Claims 1 and 11 and their dependents. For example, the Examiner has not indicated how the combination of Bhaskar and Delespaul discloses a process "wherein the dried HY-MPC is a MPC or MPI having whey proteins denatured to allow whey proteins to be incorporated into cheese in higher yield than the resulting yield when the corresponding MPC or MPI without denaturation of whey proteins is used" as claimed in Claims 1 and 11. The cheese manufacture in Bhaskar is done by standard cheddar process (page 10, lines 13-14) that involves separating the curd from the whey, and thus the whey proteins are not incorporated into the finished cheese. Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 1-11 for at least this reason.

Applicants also submit that without the knowledge in the present disclosure, a skilled artisan would not have combined Bhaskar et al. with Delespaul as the Examiner suggests. Declaration of Skelte Gerald Anema, paragraph 6. Applicants submit that there is no reason for the skilled artisan to combine the heat treatment process of Delespaul, where the heat treatment is applied as part of a cheese making process, with the MPC making process of Bhaskar.

Bhaskar focuses on providing a method of making a dried MPC for use in a *conventional* cheese making process involving separation of casein and whey. The process disclosed in Bhaskar focuses on preparation of calcium depleted MPC. Bhaskar fails to disclose a heat treatment prior to drying. Delespaul discloses a heat treatment step in the context of improving the texture of cheeses *produced by ultrafiltration*. Importantly, the heat treatment in Delespaul

is applied to the retentate or liquid starting material. Delespaul fails to disclose drying to form MPC. There is no teaching or suggestion of heat treatment in Delespaul that would be useful in forming an MPC, which is what the process in Bhaskar is used for. Because the heat treatment step in Delespaul is unrelated to forming an MPC product, there is no reason to combine the heat treatment step disclosed in Delespaul with the process disclosed in Bhaskar.

Applicants also submit that there would be no reasonable expectation of success for the combination of Bhaskar and Delespaul proposed by the Examiner. *Pharmastem Therapeutics v. Viacell, Inc.* 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007) (after *KSR*, Federal Circuit finds claims non-obvious for lack of indication of reasonable expectation of success for asserted combination).

Prior to the present invention, it would have been understood by the skilled artisan that the heating step of Delespaul, if applied to a process for making MPC such as that of Bhaskar, would make the MPC solution too viscous to dry to form a powder. Declaration of Skelte Gerald Anema, paragraph 7. A person of skill in the art would have expected the use of the heating step of Delespaul to undesirably increase the viscosity of the MPC solution and thereby prevent drying to form a powder. *Id.* Bhaskar is concerned with preparing a dried MPC that can subsequently be hydrated and processed by conventional cheese making techniques to make a cheese product. Thus, there is no reason to modify Bhaskar because of the expectation that the heat step would prevent proper formation of a dried MPC powder. In addition, for similar reasons, the skilled artisan would not have a reasonable expectation of success for using the heating step of Delespaul in the MPC process of Bhaskar for at least this reason. For the same reasons the references teach away from using a heating step in the MPC processes of Bhaskar because the skilled artisan would not expect to be able to dry the MPC to a powder.

Prior to the present invention, it would have been understood that heat treating the MPC at near neutral pH would not produce a cold soluble product. Declaration of Skelte Gerald Anema, paragraph 8. A cold soluble product is desirable in the context of MPC manufacture. *See* Bhaskar page 6, lines 34-35. The expectation of decreased cold water solubility for heat treated MPC teaches away from incorporating the heat treatment step of Delespaul with the MPC manufacturing process of Bhaskar. Further, the skilled artisan would not have had a reasonable expectation of success for producing an MPC with acceptable cold solubility properties.

Accordingly, for this reason as well, the skilled artisan would not have a reasonable expectation of success for using the heating step of Delespaul in the MPC process of Bhaskar for at least this reason.

In addition using the heat processing step of Delespaul in the processes of Bhaskar is not simply substituting steps with identifiable and predictable solutions because of the complex protein interactions and unpredictability of the changes to the protein interactions caused by denaturing and decalcifying the protein. (“[t]o the extent that an art is unpredictable, as the chemical arts often are, *KSR*’s focus on these ‘identified, predictable solutions’ may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.” *Eisai Co. Ltd. v. Dr. Reddy’s Laboratories, Ltd.*, Nos. 2007-1397, -1398, slip opinion at pg 8 (Fed Cir. 2008)). Accordingly, the skilled artisan would have no reasonable expectation of success for at least this reason.

The claimed features also solve a problem not recognized in Bhaskar and Delespaul. Prior to the present invention it was not known that reduced calcium MPC could be effective in preventing loss of the whey protein into the whey in a traditional cheese making process even if heat treated. Declaration of Skelte Gerald Anema, paragraph 9. Accordingly, Applicants request withdrawal of the rejection of for this reason as well.

In conclusion, Applicants respectfully request withdrawal of the obviousness rejections because there the combination fails to disclose the features of Claims 1-11, there is no reason to combine Bhaskar and Delespaul as suggested by the Examiner, the skilled artisan would not have had a reasonable expectation of success, and the references teach away from the combination.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution.

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Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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